RAJYA SABHA

Monday, the 25 th April, 1994, 5 *Vaishakh,* 1916 *(Saka)*

The House met at eleven of the clock. Mr. Chairman in the chair.

THE LEADER OF THE OPPOSITION (SHRI SIKANDER BAKHT) : Welcome to you, Sir.

SHRI S. JAIPAL REDDY : We welcome you.

MR. CHAIRMAN : Thank you. May (also welcome all the new Members who have taken their seats when I was away ? *(Interruptions) Quid pro quo.*

Question No. 381.

ORAL ANSWERS TO QUESTIONS

Patenting of Medicines under GATT

*381. SHRI CHIMANBHAI MEHTA: † SHRI SARADA MOHANTY :

Will the Minister of COMMERCE be pleased to state :

(a) whether it is a fact that there is no obligation under GATT to patent any existing madicine ;

(b) whether it is a fact that India would have to frame a product patent law and if so, what is the last date stipulated under GATT to frame such a law ;

(c) whether India would be in a position to produce internationally patented medicines during the transition period without the consent of patenters;

(d) whether the patenters of new medicines would have the right to price their product arbitrarily ; and

(e) if not, what is the mechanism and formula to keep their prices at a reasonable level ?

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE (SHRI KAMALUDDIM AHMED) : fa) to (e) A statement is laid on the Table of the House.

†The question was actually, asked on the floor of the House by-..Shri Chimanbhai Mehta.

Statement

Patenting of Medicines under GATT

(a) Yes Sir.

(b) Yes sir. A product-patent law covering medicines will have to be instituted in India as per the TRIPS Agreement by the end of the 10 year transition period from the coming into force of the Agreement establishing the World Trade Organisation.

(c) During the transition period manufacturers in India can produce medicines patented elsewhere without consent of the patent-holder, except those medicines which are patented after the entry into force of the agreement establishing the WTO and for which a patent application has been filed in India.

(d) and (e) The TRIPS Agreement does not prohibit the use of price control measures. The Agreement also contains other safeguards like compulsory licensing against the abuse of patent rights by the right holder.

SHRI CHIMANBHAI MEHTA : Mr. Chairman, Sir, some doubts were raised about the unlimited right of the patent-holders abroad. It was feared that they would get the freedom to exploit the Indian Market. To an extent, those fears have been dispelled.

In reply to part (c) of my question, it has been clarified that during the transition period, manufacturers in India can produce medicines patented elsewhere without consent of the patent-holder. So far, so pood. But there is a rider 'except those medicines which are patented after the entry into force of the agreement establishing the W.T.O., and for which a patent application has been field in India. Now. on the one hand, medicines need not be patented during the transition period of ten years; i.e. till 2005. But this freedom is limited by introducing another clause that the moment the W.T.O. comes into existence, manufacturers in India cannot produce medicines—even within this ten-year period—for which patents have been taken abroad. In this context.

I would like to know whether the Government of India had tried during the Uruguay Round of discussions to see that this restriction was not put so that manufacturers would have had the freedom to produce medicines patented anywhere else in the world during the ten-year period after the W.T.O. came into existence. This is the point I would like to know. Did we try to get this particular concession ?

THE MINISTRY OF COMMERCE (SHRI PRANAB MUKHERJEE) : So far as the question of efforts is concerned, as hon. Members know, before the Uruguay Round of negotiations were ultimately concluded on 15th December, the various countries stated their respective positions. We wanted to see that as far as our national laws were concerned, we protected them. In regard to what ultimately emerged after the 15th December and which was finally authenticated on the 15th April, I have stated the position. That is the position now. The position which existed before that is no longer relevant. The question is whether, after the W.T.O. comes into existence, if somebody invents a new medicine and takes a patent, that Would automatically be applicable to India or not. In this regard, while replying to part (c) of the question. I have said 'No'. He will have to file a patent application to India. They will like to do it for the Indian market. Naturally they will like to do it. If they do not do it, then, in that case, tor the interregnum, till he files an application, anybody can manufacture it.

So far as the first part of the question is concerned, that is in respect of the medicines which are in public domain now. This will be applicable to medicines which will seek patentability after the establishment of the WTO. But those medicines which are in the public domain now, could be manufactured, and that would not be a problem. This is the position.

SHRI CHIMANBHAI MEHTA : Anyway, I got some understanding on the basis of the reply given. But, from the common man's point of view, the legal questions of patent rights and patentee rights are not that important. They would like to know whether, after the patent law comes into operation, the new patent-holder who may emerge, would be able to charge arbitrary prices. If he charges arbitrary prices, what mechanism have you got to control it ? Whatever you may have suggested, according to the GATT Agreement, who would decide about the arbitrariness of the price, the Government of India or the WTO ? If they go on charging arbitrary prices which are not affordable by our people, then, have you the option to get your own compulsory licensing system put into operation ? So, you can give the licence to a local person if he wants to produce it. But the main question is about the price, how to control the price, who would be deciding about it. Is it the WTO or we who will decide the price ?

SHRI PRANAB MUKHERJEE: Of course, the price will be decided by the Government, every sovereign government. So far as the TRIPS are concerned, let me explain it to you that it provides some rights to the patent-holder. Because of his invention, it should be remunerative. That is the whole, basic objective of it. That is why, in reply to part (b) of the question, I have stated in the statement that the whole TRIPS Agreement does not prohibit the Government from introducing the price control mechanism, but we simply cannot deny the rights of the patent-holder and exploit him. If the patent-holder wants to have an arbitrary price, then, you can bring it within the domain of the public health programme. For example, a country considers a particular medicine to be important for its public health programme. That country will have the right to declare that he is demanding an exhorbitant price. The price can be raised either by manipulation of the supply-demand mechanism, by keeping the supply less than the demand, or it can be by determining a high price. The sovereign government will decide about it. The WTO will not do it. If somebody objects to that, then, he will have to go to the WTO, the dispute settlement mechanism. Automatically one cannot go to it, and there you will have to take a decision. So, that is there. But, in the laws of your own Government you will have to indicate what you have to do. When you are ggiending the laws, you will have to make provision from where a

patent holder, a right holder would know his right and how his right is going to be protected. But this right lies with the sovereign government. Nobody can arbitrarily decide the price.

SHRI SASADA MOHANTY : Chairman Saheb, I want to know from the hon. Minister whether the process patent
and the product patent will be obligatory under the GATT or not.

Part (b) of my supplementary is that the period now is ten years. The Minister has said in a public meeting that he was going to make it fourteen years. I want to know whether it will be ten years or fourteen years.

SHRI PRANAB MUKHERJEE: Sir, the hon. Member is confused between ten years and fourteen years. What I said in my public speech is that at present our patentable period is fourteen years, that this has to be amended and that according to the international law it will be twenty years. So, fourteen years is not linked with ten years. So far as the ten years period is concerned, it should be clearly understood that—I also referred to it—it is not that India doesn't allow product patent in any area. It is not the case. In certain areas, India doesn't allow product patent. That is in the areas of agricultural products, chemical products, pharmaceutical products and drugs. But in machines, we allow product patenting. There the integration period would be five years. But we allow the product patenting. Under our laws, we do not allow product patent in respect of these items which I have referred to. There the transition period would be ten years.

So far as amendments are concerned, we have to introduce certain amendments which will provide for both process patenting and product patenting as a result of this Agreement.

SHRI S. JAIPAL REDDY : Mr. Chairman, Sir, the answer given to this question is typical of the tendentious half-truths that this Government is dishing out on this entire question.

I would like to draw your attentioa to the answer given by the Government to part (d) and (e). Sir, we have read the text ourselves very carefully. Nowhere does it provide that the Government can impose price control measures. It can do so only in an emergency which would necessarily be for a short period. The answer given by the Minister suggests that we can automatically go in for compulsory licensing. The Text says that we cannot even go in for sub-licensing. Therefore I would like the Minister to explain as to how his answer is valid in the context of the GATT Text.

Secondly, Sir, he has not said anything about the process patent. The Government itself admitted on a number of occasions that 10 to 15 per cent of drugs in India would be covered under the new law. Our Indian Pharmaceutical Manufacturers' Association says, "Forty-six per cent of drugs in India would be covered." The American Pharmaceutical Manufacturers' Association say, "Sixty-six per cent of drugs in India would be covered by the new law." Which is correct?

SHRI PRANAB MUKHERJEE: Mr. Chairman, Sir, so far as reading of the Text is concerned, I will leave the judgement to the hon. Member. He says, "Nowhere in the Agreement, it allows the Government to exercise its right to determine the price." My contention is that nowhere in the Agreement it takes away the right of a sovereign Government, restricts the Government from taking action when in the Government's own opinion, the Government considers that the price is beyond the reach. In three areas, Governments are provided with adequate authority. I do not say that the hon. Member's reading is wrong. He also cannot claim that my reading is wrong. These are the areas where a targe number of cases have taken place even from 1947.

The other day, while replying to the debate on the Mexican Tuna, I had mentioned that various courts belonging to different countries have given interpretation. .. *(Interruptions)* .. Mr. Reddy, just let me complete. So far as interpretation of the Agreement is concerned, one

need not necessarily agree with that. What I am saying is that the Text doesn't prevent a Government from having a price control mechanism, if the Government of the day considers that it is necessary to protect its public health programme.

Secondly, as to how the details have been worked out, even when patent application is being made, it is not automatic that the patentability would be granted to the applicant. It will depend on the conditions which the National Government will make. If he reads article 27, clause 2 of the Agreement, there in he will find that there has been some condition that the National Governments can include in their patent law a provision to exclude the patentability. Therefore on the question whether the Government has a right or not. I will not go into that aspect. The hon. Member wanted to know whether patent holders of the new medicines would have the right to price their product. I think, I have answered that question what the machanism is, what the formula is to keep the prices at a reasonable level. I am saying repeatedly that prices can be increased by two ways. One way could be through market manipulation by supplying less than the demand. Another way could be by determining an arbitrary price. But in a competitive market, the commercial judgement of a manufacturer would be to look at the size of the market, the net profit which they may earn while determining the price of a particular unit. All these things happen and it is our day-to-day experience.

The same GATT rules book printed and published in India may cost Rs. 150. If it is printed and published in the U.S.A. — in terms of Indian Rupees—it may cost Rs. 300. In fact, I have some other book, I thought that I will bring it here. But every day we come across all these types of experiences. The same book, printed and published in some other country, may cost Rs. 350 because it depends on the capacity of the market. cost of production.

So far as royalty is concerned, patent law is essentially connected with the royalty fees. That is an element of the cost. It it not the whole cost.

SHRI S. JAIPAL REDDY: The Minister himself admitted that he was not very sure about the interpretation of the Text which he had earlier offered nor was he sure enough to question my interpretation. So, where do we find ourselves ?

MR. CHAIRMAN : Neither you nor he.. *(interruptions)*..

SHRI PRANAB MUKHERJEE : You yourself and many Members also have said that the Government has no right to make the law. You have interpreted the Constitution. As I Said, under articles 253, 73 (b) and Entry 14. I have the right *to* interpret it. Please don't interpret it in the other way and say that I was not sure. I am quite sure of mine.

MR. CHAIRMAN : I think, you have explained it properly.

SHRI G. G. SWELL: Mr. Chairman, Sir, it is abundantly clear from what the Minister said that the final authority that will make the decision would be the MTO.

SOME HON. MEMBERS : It is not MTO but WTO.

SHRI G. G. SWELL: Okay. You call it WTO. I stand corrected. He said that if the patent-holder fixes too high a price, then, the sovereign Government can tell him that he was fixing too high a price and we do not accept it. The patent-holder also doesn't accept it. Where do you go for arbitration ? You go to the WTO. It will be a long-drawn out process. However, that is not my question. You have ten years within which you can continue to produce the medicines without problems from the patent-holder. Now under this Agreement, the final Act, the patentability is for 20 years. My question is, what will hapnen after the expiry of ten years, unless before that, you have been able to introduce a law to amend your Copyright Act or your Patent laws.

He said that if the patent holder fixes too high a price, they can overcome that by compulsory licensing. Now, would he explain in what way a compulsory licensing by his Government will make any difference ?

SHRI PRANAB MUKHERJEE: Mr. Chairman, Sir, compulsory licensing

mechanism can be resorted to, if some manufacturers of a particular product manipulate the market by reducing the supply. For example, in India, we required a particular tablet say 20 billion tablets and the supply is only 1 million tablets. This shortfall will be imported. We can ask them to manufacture it in India. If they refuse to do so, we can ask some other manufacturer or company to do that. So, some compulsory licensing mechanism is possible. In respect of the non-commercial use, where the price control mechanism would come, to bring it within the public health programing and thereafter taking advantage of the non-commercial use of that particular product, we can resort to price control mechanism through which we can see that (he prices of drugs are not beyond the reach of a particular party.

So far as the international dispute settlement mechanism is concerned, the hon. Member is well aware whether it is time-consuming or not. But the answer to the limited question is that so far as this Act is concerned, it does not prevent the Government from making a law to protect the interest of the consumers and to support the public health programme. This is the limited point we have. So far as the condition period is concerned, as the hon. Member is aware copyright is under the consideration of the Select Committee ; the Trade Marks Act is under the consideration of the Select Committee. As they have mentioned, we shall have to amend the Patent Act and that fourteen-years' period will have to be extended to 20 years.

SHRI CHATURANAN MISHRA : Mr. Chairman, Sir, I want clarification from the Government on three points. My first point is this. I would like to know what the Government has done so far or proposes to do within the ten years' time that we have, to improve our research and development to such levels as we can meet the onslaughts of multinational companies.

My second point is, in our country, the Government is giving free medicines to the people through our health systems, hospitals, etc. The Chinese have done it. They would give tham free to the people under their system. Sometimes, our Government, Ministers, speak of socialism. When the Government is not going in for trade in those hospitals, what is the provision in the GATT ? Is there any restriction ? Particularly, I have in mind the medicines regarding AIDS, cancer, heart diseases, of which there are likely to be more patents from the international multi-national companies. What does the Government propose? Or, what is there in the GAIT about this? If you give it free medicines to the people, how is it affects the GATT. I think it is not affected.

The third point on which I would like an explanation from the Minister is this. When this House blocks the amendment in Patent Act proposed by the Government—this House has a right and perhaps the strength to do so-what is the provision under the rules? What has to be done in such a contingency? I have in mind the decision of the US Congress. In such a case, they went to the GATT and got it amended. Is your Government capable of doing as the Americans have done?

SHRI PRANAB MUKHERJEE: So far as the first point is concerned, I can inform the hon. Member that even this year, we are stepping up the oulay for research and development substantially. In the current Annual Plan for 1994-95, keeping in view the requirement, we have done it.

SHRI CHATURANAN MISHRA: It is very meagre.

SHRI PRANAB MUKHERJEE: What are you talking?

SHRI CHATURANAN MISHRA : One molecule requires Rs. 200-300 crores. They have provided not even Rs. 100 crores.

SHRI PRANAB MUKHERJEE: My problem with my good friend Chaturananji is that he always compares us with very rich countries. He always tries to compare two incomparable things. You have to compare what you were doing earlier in our situation with what you are doing now. It may be minuscule compared to the others. But that is a hard fact of life. You cannot ignore it. If you desire that suddenly we should be as rich as many

of the industrialised countries, we cannot. We are making adequate provisions for research and development.

In respect of public health programmes, as I have said, the Government will continue the public health programmes. I am telling you frankly that I would like to use a safeguard which is there to the effect that public health programmes should not be disturbed. To what extent the Government will be able to do it depends on the financial resources and strength of the Government of the day.

On the third aspect, I should not comment. Nobody should prejudge what this House is going to do. Both I and Mr. Mishra have been Members of this House. Of course, there was a short gap of six years. I have been in this House from 1969. Umpteen times, I have found .. .*(Interruption).*

SHRI CHATURANAN MISHRA : This is not my question.

SHRI PRANAB MUKHERJEE :... that the ruling party does not have the majority. When I was siting on that side, and Mr. L. K. Advani was the Leader of the House, they were only 70 in a House of 240 Members. But it never appeared that a Constitutional deadlock was being created by this House. When I was the Leader of the House in 1980, we were only 65. But it did not create a situation where a Constitutional deadlock was there. I cannot answer a hypothetical question as to what would happen in future if the House decides to pass an amendment. 1 am not going to answer any hypothetical question. We would consider what would happen if something happens in the House itself. *{Interruptions)*

SHRI CHATURANAN MISHRA: I never doubt the capacity of our Ministers or the Prime Minister to manage the House. Rather I was thinking that so many Prime Ministers have gone in Japan though they claim to be having high technology. In fact, they don't have that thing. They should get it from our Prime Minister and I would advise the Commerce Minister to get it patented because depite the Securities Scam and all these things, they are surviving. But my question was not that What I have said was that if such an eventuality arises— I referred to the US Congress— then what the provision is in the GATT rules ? I didn't say something hypothetical and I don't say so. I have said that this House has the power and the strength to do it. So, I gave an example of the US Congress. They have blocked it. The Minister knows much more about it than I know. He is a very experienced and learned man. So, I want to know if his learning will remain there or it will evaporate when faces U.S.A.

SHRI M. A. BABY : Sir, this is not relevant. *(Interruptions)*

SHRI PRANAB MUKHERJEE: Sir, have you allowed him ? Sir, so far as this question is concerend, I mentioned it umpteen times that this document is not a self-executing treaty. Various provisions of the Act are to be implemented through laws and Parliament has the sovereign right to pass laws or to reject them. There is no mention of what would happen when a situation arises and we will consider that situation then. GATT is not concerned with that. What Indian Parliament does or what any other sovereign Parliament will do, GATT is not concerned with and they cannot make any provisions in the GATT agreement. Even if they want to make any provision in GATT, we will straigthavvay say that this is not your domain. What our Parliament will do, is the business of our Parliament and not their business.

SHRI CHATURANAN MISHRA : I wanted to know what he is going to do in that eventuality. Whether our Government will re-negotiate or not, that was the point.

MR. CHAIRMAN : Obviously, the Government has the freedom to go there.

SHRI CHATURANAN MISHRA : All right. *(Interruptions)*

MR. CHAIRMAN : We have taken half an hour on this question. I was wanting to call you but the time has run out. Other questions are there.